



California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

NOTICE OF MEETING and AGENDA

Enforcement Committee and Work Group On E-Pedigree Meeting

Contact Person: Virginia Herold
(916) 574-7911

Date: March 11, 2009
Time: 9:30 a.m. – 4:00 p.m.
Place: Holiday Inn San Diego Bayside
4875 North Harbor Drive
San Diego, CA 92106
(619) 224-3621

This committee meeting is open to the public and will be held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Tessa Fraga at (916) 574-7912, at least five working days before the meeting.

Opportunities are provided for public comment on each agenda item. Board members who are not on the committee may also attend and comment.

MEETING AGENDA

Note: Pharmacists and pharmacy technicians who attend the full committee meeting can be awarded two hours of CE, in accordance with the board's CE policy. A maximum of four CE hours can be earned each year by attending the meetings of two different board committees.

Call to Order

9:30 a.m.

A. Workgroup on E-Pedigree

1. Discussion of Proposed Comments for FDA's Proposed Guidance for Industry on Standards for Securing the Drug Supply Chain -- Standardized Numerical Identification of Prescription Drug Packages
2. Discussion of Comments for FDA's Proposed Guidance for Industry on Unique Device Identification Systems
3. Discussion and Updates to Implement Electronic Pedigree Requirements -- Presentations by:
 - Federal Food and Drug Administration
 - Congressman Buyer's Office
 - GS1
 - Oracle
 - Other Interested Manufacturers, Wholesalers, Pharmacies and Their Associations

B. Enforcement Committee

1. Discussion of Policies Involving Home Generated Pharmaceutical Waste Take Back by Pharmacies
 - Model Guidelines for Home Generated Pharmaceutical Waste Approved by the California Integrated Waste Management Board (February 2009)
 - Senate Bill 26

Agenda Continues on Second Page

- Comments Sought by the Federal Drug Enforcement Administration on Disposal of Controlled Substances by Persons Not Registered with the DEA – Docket No. DEA-316 A
- 2. Update on Activities to Implement E-Prescribing in California
- 3. California's Controlled Substance Utilization Review and Evaluation System (CURES), a presentation and question and answer session led by Department of Justice, Bureau of Narcotics Enforcement
 - Implementation Issues Surrounding the New Data Collection Vendor for CURES
 - Moving to Provide Online, Near Real Time Reports to Practitioners on Controlled Substances Dispensed to Patients by July 1, 2009
- 5. Update Regarding Arrests and Criminal Convictions of Board Applicants and Licensees
- 6. Department of Consumer Affairs' Policies Regarding Pursuit of Interim Suspension Orders Discussion
- 7. Public Comment for Items Not on the Agenda*

* *(Note: the committee may not discuss or take action on any matter raised during the Public Comment section that is not included on this agenda, except to decide to place the matter on the agenda of a future meeting. Government Code Sections 11125 and 11125.7(a))*

Adjournment

Note: Adjournment time is approximate

4:00 p.m.

Meeting materials will be available from the board's Web site by March 6, 2009